

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

ANTHONY DeGIDIO,)	CASE NO. 3:09-CV-00721
)	
Plaintiff,)	JUDGE JAMES G. CARR
)	
v.)	
)	
CENTOCOR, INC., JOHNSON &)	
JOHNSON, ORTHO-McNEIL)	
PHARMACEUTICAL, INC., JOHN DOE)	
MANUFACTURERS A-Z, JOHN DOE)	
DISTRIBUTORS A-Z, RAY MILLER, D.O.,)	
AND JANE DOE,)	
)	
Defendants.)	

**DEFENDANTS CENTOCOR ORTHO BIOTECH INC., JOHNSON & JOHNSON, AND
ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.'S REPLY TO PLAINTIFF'S
OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

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I. INTRODUCTION AND SUMMARY OF THE ARGUMENTS

Many of the alleged facts in Plaintiff's Opposition lack evidentiary support, particularly those concerning Plaintiff's attempts to define or explain the medical issues in this case and what various physicians thought, believed, or reviewed when treating or diagnosing Plaintiff. Any such information should be disregarded, as Plaintiff and his counsel are not qualified to explain such matters, nor do they know the thoughts or motives of medical personnel. Indeed, as the non-moving party, Plaintiff must submit evidence under Federal Rule of Civil Procedure 56(c) supporting his position. *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986).

Even if such facts are true, however, Plaintiff still cannot refute the arguments Defendants raised in support of their Motion. Plaintiff's Opposition confirms that the interstitial pneumonitis he allegedly experienced was in fact discussed in Remicade®'s labeling. He contends that the label is inadequate, however, because it "assures" physicians that Remicade® does not cause interstitial pneumonitis. Plaintiff's inadequate warning claim fails as a matter of law because (1) he provides no expert support for his claim, (2) the Remicade® label warns of Plaintiff's alleged condition, (3) he provides no admissible evidence sufficient to demonstrate a genuine issue of material fact, (4) the plain meaning of the Remicade® label refutes his position, (5) the labeling is consistent with regulatory authority and legal precedent, and (6) Plaintiff was provided a reasonable warning under Ohio law.

Plaintiff's inadequate warning claim also fails as a matter of law because Dr. Slee, the only intermediary between Defendants and Plaintiff, testified unequivocally that he would not have communicated a warning for interstitial lung disease, and specifically eosinophilic pneumonia ("EP"), even if there was a "known" causal relationship between this condition and Remicade®. Furthermore, Dr. Slee, the only expert Plaintiff uses to support his inadequate warning claim, testified that Plaintiff's pneumonia was a rare, idiosyncratic reaction to

Remicade®. Plaintiff's questions to Dr. Slee involving a completely unsupported, hypothetical, and ambiguous "significant" causal relationship between Remicade® and interstitial lung disease, specifically EP, does not change this reality.

Plaintiff's fraud and conspiracy and commercial bribery claims fail because Plaintiff has not alleged the basis for these claims, and cannot provide evidence to support them. Furthermore, recent authority from this Court indicates that these claims should be dismissed because they are abrogated by Ohio's Product Liability Act ("OPLA").

Lastly, judgment should be entered in Defendants' favor as to Plaintiff's design defect and failure to conform claims because Plaintiff has not opposed Defendants' request for summary judgment on these claims.

Defendants respectfully disagree with Plaintiff's characterization of the two-stage dispositive briefing in this case to the extent Plaintiff is using it as an excuse for not having sufficient evidentiary support to substantiate his failure to warn claim, especially from outside sources. *See* Opp. at 1-2. The Court established a specific discovery deadline for this initial dispositive motion, and Defendants did not seek to limit Plaintiff's discovery efforts during this period. Defendants assume that Plaintiff's reliance on Dr. Slee as his sole expert concerning the product labeling at issue is intentional. Nonetheless, when lacking evidentiary support, a non-moving party should follow the procedures set forth in Federal Rule of Civil Procedure 56(f).

II. PLAINTIFF'S WARNING CLAIMS FAIL AS A MATTER OF LAW BECAUSE PLAINTIFF LACKS EXPERT TESTIMONY TO ESTABLISH THESE CLAIMS.

Plaintiff has not offered any expert support opining that the Remicade® label is inadequate. To survive summary judgment, however, Plaintiff must establish the inadequacy of any warning through expert medical testimony. *Saraney v. Tap Pharmaceutical Prod.*, 2007 WL 148845, *6, FN3 (N.D. Ohio), citing *Graham v. Am. Cyanimid Co.*, 350 F.3d 496, 514 (6th Cir.

2003). Here, Plaintiff's designated expert, Dr. Slee, never once criticized Defendants' label or suggested that it was in any respect inadequate. Thus, as explained in more detail below, Defendants are entitled to summary judgment on Plaintiff's failure to warn and design defect claims.

Plaintiff goes to great lengths to point out Dr. Slee's testimony that the Remicade® label does not include the specific terms "non-infectious interstitial lung disease (NILD) and/or EP." Opp. at 20-22. Plaintiff presents this evidence as expert testimony on the "deficiencies in Defendants' warning label." *Id.* at 19. Yet, Dr. Slee did not criticize this fact or even remotely opine that the label should warn of eosinophilic pneumonia and/or Plaintiff's latest term of choice, "Non-infectious interstitial lung disease."¹ To the contrary, Dr. Slee testified unequivocally that, even now, he believes the Remicade® labeling adequately warns physicians about the risks of Remicade®, and that he does not have any criticism of the label. Motion at 7, 14-15. Moreover, he testified that his understanding of Remicade®'s risks comes not only from company-provided information, but also his own prescribing experience, American Seminar tapes, attending conferences, participation in two professional organizations, an online drug compendium, and peer review. Motion at 7, citing Slee depo at 44, 47, 50-51.

Thus, the only expert Plaintiff provides to refute Defendants' claim that the Remicade® warning is adequate actually agrees with Defendants on this issue, and formed his opinion from many different sources. Furthermore, although Plaintiff argues that even "a cursory review of published literature" demonstrates the need for a warning concerning a "potential" "causal link"

¹ Plaintiff's terminology used to describe the condition he alleges should have been contained in the Remicade® labeling has changed throughout this litigation. His Complaint focused on the term "acute eosinophilic pneumonia." Presumably because Defendants pointed out that the Remicade® label warns about pneumonia, Plaintiff's counsel repeatedly used the phrase "interstitial lung disease and/or EP" while questioning Dr. Slee at his deposition. Now, after Dr. Slee testified that interstitial lung disease and EP can have both infectious and non-infectious etiologies (Motion at 7), Plaintiff argues for the first time that the Remicade® label should have warned specifically of "non-infectious interstitial lung disease and/or eosinophilic pneumonitis." Opp. at 3.

between Remicade® and NILD and/or EP, Plaintiff has not offered any expert support for this argument either. Accordingly, Plaintiff's lack of supportive expert testimony on the adequacy of Defendants' warning is fatal to his warning and design defect claims, entitling Defendants to judgment as a matter of law.

III. PLAINTIFF'S WARNING CLAIMS FAIL AS A MATTER OF LAW BECAUSE PLAINTIFF STILL CANNOT SHOW THAT DR. SLEE WOULD HAVE GIVEN A DIFFERENT WARNING SUPPORTED BY THE EVIDENCE.

The testimony of Dr. Slee quoted by Plaintiff does not at all change Dr. Slee's unambiguous testimony that he would not have discussed the risk of "interstitial lung disease, specifically EP" with Plaintiff. Dr. Slee stated definitively that Plaintiff experienced a "*rare idiosyncratic reaction*" and not one that I probably would've entertained in my discussion with the patients." Opp. at 25 (emphasis added). According to Dr. Slee, even if there was a "known relationship" between "Remicade® and interstitial lung disease, specifically EP" he would "probably not" communicate that warning to his patients.² *Id.*

Indeed, Defendants demonstrated in detail how Dr. Slee - who is very knowledgeable of Remicade®'s risks, and especially various forms of pneumonia - testified that he does not go into detail about different types or causes of pneumonia with his patients, preferring instead to use lay terms and discuss categories of risks. Motion at 7-8, 18. For example, Dr. Slee testified that he is well aware that lupus is discussed in the Remicade® labeling and can cause autoimmune lung disease, but that he does not get into this type of "minutia" with patients. Motion, Exh. B at 219-222.

To deal with Dr. Slee's devastating testimony, Plaintiff created a hypothetical at Dr. Slee's deposition in which, (1) Remicade® "had been determined to present a "*significant risk*"

² This testimony completely contradicts Plaintiff's statement that Dr. Slee would have warned of a "known" risk. Opp. at 5.

of causing interstitial lung disease, specifically EP; and (2) such “significant” risk was *required* to be in “certain medication guides or in the information form, consent form, given to patients.” *Id.* Dr. Slee then pointed out that Plaintiff’s counsel presented a new hypothetical before saying that under this different scenario he would discuss such “significant risks” with Plaintiff. *Id.*

Yet Plaintiff has submitted absolutely no admissible evidence whatsoever to show even a “known risk” of interstitial pneumonia beyond that already discussed in the Remicade® label, let alone the “significant risk” hypothetically presented to Dr. Slee.³ For example, Plaintiff does not provide any expert testimony concerning the incidence or prevalence of interstitial pneumonia, specifically EP, and no federal regulatory documents concerning such a risk, including any requirement for additional warning. As discussed below, even the five articles attached to Plaintiff’s Opposition – again, without expert support – do not demonstrate, let alone prove, a causal relationship between interstitial pneumonia, specifically EP, and Remicade® rising to the level of a “significant risk” with “required” additional warning. Accordingly, Plaintiff cannot meet his burden to show that Dr. Slee would have changed his decision to prescribe Remicade® or would have provided the warning Plaintiff argues he should have been given.

IV. DEFENDANTS’ WARNINGS ARE ADEQUATE AS A MATTER OF LAW BECAUSE THE LABEL SPECIFICALLY AND ACCURATELY DISCLOSES THE TYPE OF PNEUMONIA EXPERIENCED BY PLAINTIFF – INTERSTITIAL PNEUMONITIS.

A. The Remicade® label warns of the type of pneumonia experienced by Plaintiff.

Despite the various terminology used by Plaintiff to identify the type of pneumonia he experienced and that allegedly should have been included in the Remicade® warnings⁴, his

³ In his Opposition, Plaintiff unjustifiably referred to his “significant risk” hypothetical as a discussion of an “established risk.” Opp. at 26. Plaintiff did not use the term “established” at Dr. Slee’s deposition, nor is it accurate or appropriate to broaden the hypothetical’s meaning in his Opposition.

⁴ See FN 1, *supra*.

Opposition confirms that Defendants did in fact warn about the pneumonia he allegedly experienced – interstitial pneumonitis. As Defendants pointed out in their Motion, Dr. Slee testified that the “interstitial pneumonitis” discussed in the Remicade® label is the same condition experienced by Plaintiff.⁵ Motion at 7. Plaintiff does not dispute that fact, and, actually, acknowledges that this warning deals with non-infectious interstitial lung disease. Opp. at 3, 9, 17. Surely, Plaintiff cannot claim that a NILD warning is missing from the label, while simultaneously criticizing the label’s discussion of NILD.

B. Plaintiff’s criticism of the interstitial pneumonia warning does not create a fact issue.

Plaintiff’s issue, therefore, is not that Defendants did not warn of the risk of interstitial lung disease, and particularly interstitial pneumonia, but that the warning “assured prescribing physicians that there was no known causal connection between the drug and interstitial lung disease.” Opp. at 9. For the following reasons however, this alleged inadequacy does not present a genuine issue of material fact.

First, Plaintiff flatly misstates the meaning of the warning, which is copied below:

The following adverse events have been reported during post-approval use of REMICADE® ... interstitial pneumonitis/fibrosis ... Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to REMICADE® exposure.

This warning plainly does not “assure” either a causal or lack of causal relationship; it simply discloses that interstitial pneumonitis has been reported, and explains the limitations of voluntary case reports.

⁵Plaintiff repeatedly claims that Defendants failed to mention Remicade®’s interstitial pneumonia warning in their Motion. Plaintiff is incorrect, as Defendants discussed the interstitial pneumonia warning on pages 6, 7, 13, and 14 of their Motion.

Second, adverse event reports cannot reliably establish causation, and therefore cannot be used to claim a causal relationship in a warning label. This issue has been resolved in courts throughout the country. *See, e.g., In re Meridia Products Liability Litigation*, 328 F. Supp.2d 791, 808 (N.D. Ohio 2004) (case reports “do not screen out alternative causes for the adverse event and often lack analysis,” are “not scientifically valid proof of causation” and are “irrelevant to establish a material issue of fact.”), citing *Rider v. Sandoz Pharms. Corp.*, 295 F.3d 1194, 1199 (11th Cir.2002), *Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir.2001); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1250 (11th Cir. 2005) (“Uncontrolled anecdotal information [in FDA adverse event reports] offers one of the least reliable sources to justify opinions about both general and individual causation.”); *Glastetter*, 252 F.3d at 989-90 (8th Cir. 2001) (case reports are “simply a doctor’s account of a particular patient’s reaction to a drug or other stimulus, accompanied by a description of the relevant surrounding circumstances. Case reports make little attempt to screen out alternative causes for a patient’s condition. They frequently lack analysis. And they often omit relevant facts about the patient’s condition.”); *Meister v. Med. Eng’g Corp.*, 267 F.3d 1123, 1129 (D.C. Cir. 2001) (case reports cannot establish general causation); *Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1034 (S.D. Ill. 2001) (“case reports do not provide reliable foundation for a causation opinion”); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156-57 (D. Mont. 1999) (“Correlation of two events in time does not necessarily establish causation. That is why anecdotal reports are not generally accepted as reliable scientific evidence to establish causation.”); *Saari v. Merck & Co., Inc.*, 961 F. Supp. 387, 394 (N.D.N.Y. 1997) (MedWatch reports are particularly unreliable because they are merely a compilation of perceived patient reactions that “neither confir[m] nor den[y] that there is any relationship” between alleged

symptoms and a medication); *Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) ("case reports are not reliable scientific evidence of causation, because they simply describ[e] reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation"); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999); *Richardson v. Richardson-Merrell, Inc.*, 649 F. Supp. 799, 801 n.5 (D.D.C. 1986), *aff'd*, 857 F.2d 823 (D.C. Cir. 1988), *cert. denied*, 493 U.S. 882 (1989) (AERs "are neither exceptions to the hearsay rule nor data reasonably relied upon by experts in the field of making determinations of causality.").

The FDA likewise recognizes the inherent pitfalls associated with considering adverse event reports as evidence of causation:

[O]ne or even many reports of adverse reactions often do not provide sufficient information to confirm that a drug caused the reaction. A reaction may be caused by the suspect drug, another drug that a patient is taking, or the underlying diseases for which the drug was prescribed; it may also be entirely coincidental.

Dr. Gerald Faich, *Adverse Drug Reaction Monitoring*, New Eng. J. Med. 314(24) 1589, 1591 (1986); *see also In re Bayer AG Secs. Litig.*, No. 03-Civ-1546, 2004 WL 2190357, at *9 (S.D.N.Y. Sept. 30, 2004) (AERs "may not establish a nexus between a drug and the reported illness") (citing 21 C.F.R. § 314.80(a) (2006)).

The FDA also cautions against drawing any inference of causation from a count of the number of reports: "For postmarketing reporting, the impetus for reporting, the frequency with which a suspected adverse reaction is reported, and the number of exposures to the drug compared to the number of suspected reactions reported are unknown, making estimation of incidence calculations difficult." 71 Fed. Reg. 3922, 3950 (Jan. 24, 2006). Indeed, the FDA

views post-marketing reports as “quite subjective and imprecise.” *See* Food and Drug Administration, *The Clinical Impact of Adverse Event Reporting* at 5 (Oct. 1996), available at <http://www.fda.gov/downloads/Safety/MedWatch/UCM168505.pdf> (last visited Aug. 13, 2010).

Thus, Plaintiff cannot create a fact issue with the Remicade® warning by attaching or otherwise referencing inadmissible adverse event reports as proof of a causal connection or adverse event frequency – especially without expert support as discussed above. Nor can Plaintiff create a fact issue by claiming that the warning “assures” there is no causal connection when it justifiably states that causation simply cannot be established because of shortcomings inherent to the reports. Accordingly, Defendants warned of the potential risk of Plaintiff’s alleged condition – interstitial pneumonitis – in a manner consistent with their regulatory obligations and legal precedent.

C. Remicade®’s infectious pneumonia and interstitial pneumonia warnings are consistent with Defendants’ arguments concerning the adequacy and reasonableness of the warnings given to Plaintiff.

Plaintiff misses the point when he states that Defendants argue that infectious pneumonia discussed in the Remicade® label is the same as the “non-infectious” interstitial pneumonia he contracted. *Opp.* at 3, 17-18. Defendants never made such a statement. Defendants’ point, rather, is that Dr. Slee’s warning to Plaintiff – a risk of death from pneumonia – constitutes a *reasonable* warning under Ohio law.

Dr. Slee testified that it is “well known” that interstitial pneumonia, including eosinophilic pneumonia, can be caused by an allergic reaction *or infection*.⁶ *Motion* at 7. Plaintiff does not dispute that he accepted the risk of pneumonia prior to receiving Remicade®. *Motion* at 8; *Opp.* at 10. Thus, Plaintiff essentially claims that he assumed the risk of death from

⁶ Once again, Plaintiff cites to Dr. Slee’s testimony to support a proposition that is exactly the opposite of what he said. *See Opp.* at 7-8, claiming that NILD is not caused by infection.

interstitial pneumonia of infectious etiology (the greater risk as evidenced by Defendant's black box pneumonia warning), but did not assume such a risk from interstitial pneumonia of autoimmune etiology. To allow Plaintiff's warning claims to proceed under this novel theory would indeed transfer the analysis of an adequate warning from a focus on the potential side effect to its etiology. There simply is no precedent for this in Ohio.

Finally, Plaintiff's portrayal of various physicians being deceived by Remicade®'s labeling while attempting to diagnose his condition is an inaccurate, completely unsupported, premature, red-herring issue. These physicians do not operate in a vacuum, completely isolated from any source of information beyond the Remicade® label, as described by Plaintiff. Plaintiff provides no evidence whatsoever about what these doctors knew, said, or consulted. Even if Plaintiff's story were true, it does not have any bearing on what Plaintiff and Dr. Slee discussed and knew at the time Plaintiff was treated with Remicade®, and is therefore irrelevant to the issues ripe for decision in Defendants' Motion.

V. **PLAINTIFF'S FRAUD CLAIM FAILS BECAUSE THE SINGLE FRAUDULENT ACT HE ALLEGES IS REFUTED BY THE EVIDENCE, NO OTHER EVIDENCE OF FRAUD IS PRESENTED, AND IT IS ABROGATED BY THE OPLA.**

In support of his fraud claim, Plaintiff merely cites to his Complaint – as he did at his deposition and in his discovery responses. Federal Rule of Civil Procedure 56(e)(2), however, requires a party opposing summary judgment to respond beyond a reliance on his own pleadings and to set forth specific facts showing a genuine issue for trial.

Nonetheless, even Plaintiff's reference to his pleadings demonstrates there is no genuine issue of material fact to support his fraud claim. Specifically, he states that Defendants "failed to disclose the fact that NILD was a known adverse reaction to Remicade® therapy." This fact, however, is refuted by the evidence. As explained above, Defendants did in fact warn of NILD when they disclosed the risk of interstitial pneumonitis. See p. 5, *supra*, showing how Plaintiff

treats the Remicade® label's interstitial pneumonitis discussion as a statement about NILD.

In response to Defendants' criticism of the lack of detail in Plaintiff's Complaint, Plaintiff claims that he pleaded fraud with particularity, and provides no other specific facts to support this claim. Missing from his pleadings and Opposition, however, are any allegations of specific fraudulent conduct, including specifically who was involved, where it occurred, when it occurred, or how it occurred. Indeed, Plaintiff was provided with hundreds if not thousands of documents from Defendants and Dr. Slee, and still cannot show one instance of fraudulent conduct. This is not surprising, as Plaintiff testified that he could not even remember discussing Remicade® with Dr. Slee and had no support for fraud outside the allegations of his Complaint. Motion at 20-22, 24.

Finally, Plaintiff's fraud claim is abrogated by the OPLA. Defendants did not previously move to dismiss Plaintiff's fraud claim on this basis because of prior negative precedent. However, two Northern District of Ohio decisions made available after Defendants had researched this issue indicate that fraud claims may be abrogated by the OPLA. *See* FN 7 and abrogation discussion, pp. 11-13, *infra*.

For all of the above reasons, including those set forth in Defendants' Motion, Plaintiff's fraud claim fails as a matter of law.

VI. PLAINTIFF'S "CIVIL CONSPIRACY AND COMMERCIAL BRIBERY" CLAIM FAILS BECAUSE PLAINTIFF HAS NOT ALLEGED THE BASIS OR PROVIDED EVIDENTIARY SUPPORT FOR THIS CLAIM, AND IT IS ABROGATED BY THE OPLA.

A. Plaintiff's failure to sufficiently allege and support "civil conspiracy and commercial bribery"

As with his fraud claim, Plaintiff fails to specifically identify the basis or provide evidentiary support for his "civil conspiracy and commercial bribery" claim. He does not identify who the conspirators are, what they did, where, when, how, etc. Instead, Plaintiff

merely quotes his ambiguous “commercial bribery” allegations from his Complaint. Opp. at 27.

Plaintiff further confuses the issue by claiming that Defendants’ warnings are “one viable basis” for this claim, while failing to plead in his Complaint or evidence in his Opposition how this is so. *Id.* at 28. Defendants still cannot make any sense out of this claim, and their Motion has not prompted any further evidence or explanation from Plaintiff.

Consequently, Defendants reiterate that Plaintiff’s pleadings are deficient because of his failure to plead and support (1) the “independent unlawful act or tort” forming the basis for this claim, and (2) a cause of action for “commercial bribery” in Ohio that can serve as the requisite unlawful act for a civil conspiracy claim. To the extent the unlawful act is one of the causes of action forming Plaintiff’s Complaint, Defendants request summary judgment because these claims fail as a matter of law and therefore cannot support a civil conspiracy cause of action.

B. Abrogation by the OPLA

Plaintiff claims that his civil conspiracy and commercial bribery claim is not abrogated by the OPLA because it “arises out of the fraudulent actions of Defendants relating to Remicade®.” Opp. at 29, citing *CCB Ohio LLC v. Chemque Inc.*, 49 F.Supp.2d 757, 763-64 (S.D. Ohio 2009). In *this* Court, however, a common law product liability claim involving fraud may be abrogated by the OPLA. Two recent decisions⁷ seem to endorse, without qualification, abrogation of any common law product liability claim. *See Crisp v. Stryker Corp.*, 2010 WL 2076796, *1 FN4, *3 (N.D. Ohio, May 21, 2010) (dismissing seven common law product liability claims, including Fraudulent Concealment, Fraudulent Misrepresentation, and Fraud and Deceit, with opportunity to replead, if possible, under an appropriate section of the OPLA);

⁷ Neither of these two decisions were made available on Westlaw when Defendants researched and briefed their Motion. Westlaw confirmed that *Crisp* was made available on May 27, 2010, just four days before Defendants filed their Motion, and after Defendants had researched the issue of OPLA abrogation. *See* Email from Westlaw, attached as Exh. A.

Friedman v. Intervet Inc., 2010 WL 2817257, *6 (N.D. Ohio, July 16, 2010) (“To be sure, the OPLA preempts all claims that might arise under Ohio common law and statutes.”); *compare Boroff v. Alza Corp.*, 2010 WL 395211, *7 (N.D. Ohio) (finding fraudulent misrepresentation claim not abrogated, but citing support from 1998 case that analyzed pre-2005 version of the OPLA), *with Miles v. Raymond Corp.*, 612 F.Supp.2d 913, 923, FN8 (N.D. Ohio 2009) (disapproving reliance on any case that considered prior versions of the OPLA).

Defendants contend that the OPLA is clear, contains no qualifications, and hails from a legislative history in which it has been redrafted to be more inclusive in response to judicial limitation. *See Miles*, 612 F.Supp.2d at 920 ([T]he language of § 2307.71(B) clearly proclaims the legislature's specific intention to eliminate common law product liability causes of action. ... [It] provides a clear and unequivocal statement of the legislature's intent, which must be given effect.). Therefore, the OPLA should abrogate Plaintiff's civil conspiracy and commercial bribery claim regardless of the underlying theory from which Plaintiff claims it arises.

Lastly, even if certain common law claims are not abrogated by the statute, Plaintiff's claim should be abrogated because the alleged underlying fraudulent conduct is based on the propriety of Defendants' warnings. *See* p.10, *supra*. Under Ohio law, the *substance* of the claim, not the manner in which it is pleaded, determines how it is treated. *Miles*, 612 F.Supp.2d at 921. Thus, Plaintiff's bald allegations of an “intent to mislead” cannot turn a failure to warn claim into common law fraud. Accordingly, Plaintiff's civil conspiracy and commercial bribery claim amounts to an inadequate warning claim abrogated by the OPLA.

VII. PLAINTIFF DOES NOT DISPUTE DEFENDANTS' REQUEST FOR SUMMARY JUDGMENT AS TO PLAINTIFF'S DESIGN DEFECT AND FAILURE TO CONFORM CLAIMS.

For the reasons stated in Defendants' Motion, and because Plaintiff has presented no opposition, Defendants respectfully request summary judgment on Plaintiff's design defect and

failure to conform claims.

VIII. CONCLUSION

For the reasons stated above and presented in Defendants' Motion, Defendants respectfully request judgment, or dismissal (as appropriate), in their favor as to all of Plaintiff's claims.

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that that this case has been assigned to the complex track and that it adheres to the page limitations set forth in LR 7.1(f), as modified by this Court in its February 2, 2010 entry.

/s/ Justin E. Rice

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CERTIFICATE OF SERVICE

I hereby certify that on August 13, 2010 a copy of the foregoing **Defendants Centocor Ortho Biotech Inc., Johnson & Johnson, and Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Reply to Plaintiff's Opposition to Defendants' Motion for Summary Judgment** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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